

Remarks/Arguments

Claims 44-46, 50 and 51 are pending in this application and are rejected under 35 U.S.C. §102(a) or under 35 U.S.C. §103(a) over WO98/39443 - Gebe et al. This rejection is respectfully traversed.

Applicants have amended claim 44 to remove the functional recitation that was erroneously added to the claim during an earlier amendment. Applicants believe that this amendment does not impact the allowability of claim 44 since amended claim 44 is still novel and non-obvious, as explained below. No new matter is added by this amendment.

Claim Rejections – 35 USC § 102(a) and 103(a)

Claims 44-46, 50 and 51 remain rejected under 35 U.S.C. §102(a) as being anticipated by, or, in the alternative, under 35 U.S.C. §103(a) as obvious over, WO 98/39443 (11 September 1998)- Gebe et al.

The claims pending in this application, in their broadest aspect, are directed to the polypeptide of SEQ ID NO: 148.

Gebe et al. discloses a polynucleotide sequence with 99.7% sequence similarity to the nucleic acid sequence of SEQ ID NO: 147 that codes for the claimed polypeptide of SEQ ID NO: 148. While the Gebe et al. polypeptide sequence ends with a Gly residue (encoded by codon GGA), the last residue in SEQ ID NO: 148 is Val (encoded by codon GTG). Hence, the polynucleotide sequence of Gebe et al. encodes a polypeptide of 347 amino acids, which differs from the polypeptide of SEQ ID NO: 148 of the present application in its last amino acid residue. Although, if the sequence of the nucleic acid of SEQ ID NO: 147 is correct, Gebe et al. does not anticipate any of the claims pending, the Examiner has raised the question whether the sequence difference is real or is due to a sequencing error.

Previously, Applicants submitted evidence showing a comparison between the prior art Gebe sequence with the DNA33100 sequence encoding the present polypeptide and indicated that the difference between the two nucleic acid sequences was due to alternative splicing. The Examiner did not find this evidence persuasive for overcoming the above rejections and

requested further proof showing that there was no sequencing error in the sequence of SEQ ID NO: 147 of the present invention.

Along with the present Amendment and Response, Applicants submit a Declaration by Dr. Audrey Goddard which provides details of the sequencing of DNA33200 (SEQ ID NO: 147) that encodes the presently claimed polypeptide. According to the Declaration, the sequence of DNA33200 was determined at the "Sequencing Core Facility" at Genentech, Inc., using the ABI3700 capillary electrophoresis sequencer. As explained in detail in the declaration, Exhibit A provides chromatograph traces of DNA33200 sequencing and Exhibit B provides a textual readout of the chromatograph traces of Exhibit A. From these data, it is clearly evident that the codon encoding the last amino acid of SEQ ID NO: 148 was indeed "GTG" and not "GGA", as in the Gebe sequence. This evidence proves that the claimed DNA 33100 sequence is different from the Gebe sequence and is without any sequencing error, contrary to the Examiner's suggestion in the Office Action. Accordingly, Gebe is not a valid 102(b) reference and the rejections under 102(b) should be withdrawn. Since there is nothing in Gebe *et al.* that would suggest the existence of a variant polypeptide sequence like that of the present application, the Examiner is further requested to similarly withdraw the rejections under 35 USC 103(a) to claims 44-46, 50 and 55-58, and the objection to Claim 49.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C9). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

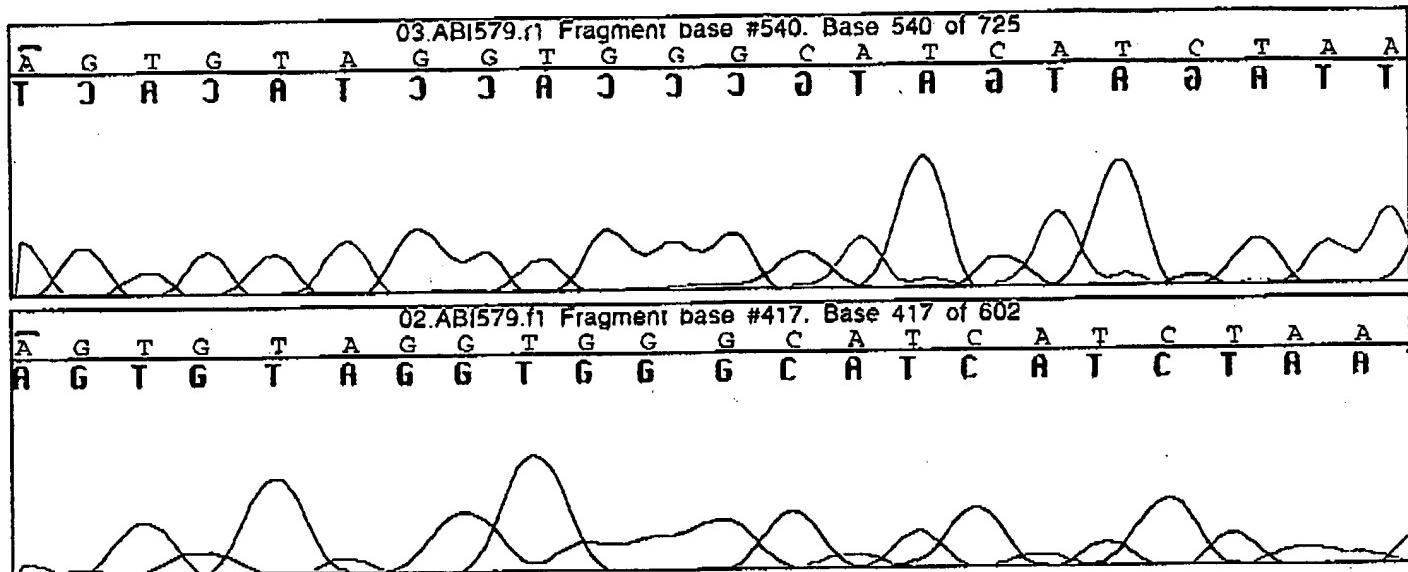
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Chromatograms from 33100
Sequencher™ "Untitled Project"



33100

Sequencher™ "Untitled Project"

◀ 03.ABI579.r1 #373 CTCTCTCCCT CCTTCAGAGA CCGGAAATGC TATGGCCCTG
◀ 02.ABI579.f1 #250 CTCTCTCCCT CCTTCAGAGA CCGGAAATGC TATGGCCCTG

#1041 CTCTCTCCCT CCTTCAGAGA CCGGAAATGC TATGGCCCTG

◀ 03.ABI579.r1 #413 GGGTTGGCCG CATCTGGCTG GATAATGTTC GTTGCTCAGG
◀ 02.ABI579.f1 #290 GGGTTGGCCG CATCTGGCTG GATAATGTTC GTTGCTCAGG

#1081 GGGTTGGCCG CATCTGGCTG GATAATGTTC GTTGCTCAGG

◀ 03.ABI579.r1 #453 GGAGGAGCAG TCCCTGGAGC AGTGCCAGCA CAGATTTGG
◀ 02.ABI579.f1 #330 GGAGGAGCAG TCCCTGGAGC AGTGCCAGCA CAGATTTGG

#1121 GGAGGAGCAG TCCCTGGAGC AGTGCCAGCA CAGATTTGG

◀ 03.ABI579.r1 #493 GGGTTTCACG ACTGCACCCA CCAGGAAGAT GTGGCTGTCA
◀ 02.ABI579.f1 #370 GGGTTTCACG ACTGCACCCA CCAGGAAGAT GTGGCTGTCA

#1161 GGGTTTCACG ACTGCACCCA CCAGGAAGAT GTGGCTGTCA

◀ 03.ABI579.r1 #533 TCTGCTCAGT GTAGGTGGGC ATCATCTAAT CTGTTGAGTG
◀ 02.ABI579.f1 #410 TCTGCTCAGT GTAGGTGGGC ATCATCTAAT CTGTTGAGTG

#1201 TCTGCTCAGT GTAGGTGGGC ATCATCTAAT CTGTTGAGTG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ashkenazi et al. Docket No: 39780-1618P2C9
Serial No: 09/904,462 Group Art Unit: 1646
Filed: July 13, 2001 Examiner: Jiang, Dong
For: PRO229 POLYPEPTIDES

DECLARATION OF DR. AUDREY GODDARD UNDER 37 C.F.R. § 1.132

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

- I, AUDREY GODDARD, do declare and say as follows:
1. I am an inventor of the above-identified patent application.
 2. I am a Senior Clinical Scientist at the BioOncology, Medical Affairs Department of Genentech, Inc., South San Francisco, California 94080.
 3. Between 1993 and 2001, I headed the DNA Sequencing Laboratory at the Molecular Biology Department of Genentech, Inc. During this time, my responsibilities included the identification and characterization of genes contributing to the oncogenic process, and determination of the chromosomal localization of novel genes.
 4. My scientific Curriculum Vitae, including my list of publications, is attached to and forms part of this Declaration (Exhibit C).
 5. I am familiar with the pending claims in the above-identified patent application and also, in pending U.S. application 09/906,618, both of which pertain to SEQ ID NO: 147 shown in Figure 53 of the specification.
 6. Prior to the deposition of DNA33100 with the ATCC on November 14, 1997 (ATCC accession number 209377), its DNA sequence was verified at our dedicated Sequencing Core Facility. Sequencing of all clones was routinely performed at least two times and if consistent results were obtained, the clones were deposited with the ATCC.

PCR was used to amplify and fluorescently label the sample DNA33100 using Big Dye™ reagents from Applied Biosystems (ABI). After PCR, the reactions were loaded onto an ABI 3700 capillary electrophoresis machine where, following electrophoretic separation, fluorescently labeled nucleotide bases were excited by a laser and "read" by a computer running the Data Collection Version 3.0 software (ABI). The Data Collection program generated a chromatographic trace as shown in Exhibit A, submitted herewith for DNA33100. The Sequencher© 4.2 program (Gene Codes Corp.) was used to compile the chromatographic traces into the final sequence. We then used the "GSeq Edit program" to obtain a textual readout of the Sequencher© chromatograph shown in Exhibit B.

7. The attached exhibits show the nucleotide sequence determined for DNA33100 around the "TAG" stop codon region. Exhibit A shows the results of sequencing performed in two separate PCR reactions; first, using a reverse primer (top panel: 03.AB1579.r1), and second, using a forward primer (bottom panel: 03.AB1579.f1). Based on the chromatographic peaks shown in the bottom panel, it is evident that the codon just before the stop codon "TAG" is "GTG". This sequence was once again reiterated in the sequencing reaction using the 'reverse' primer which sequenced the anti-sense strand whose complement gave a sequence identical to that generated with the forward primer (top panel, top line of Exhibit A). The "GSeq Edit" readouts corresponding to the chromatographs set forth in Exhibit A are depicted in Exhibit B. Here, at lines 13 (see nucleic acid residue number 541-543) and 14 (see nucleic acid residue number 418-420), the read-outs confirm that the codon before the stop codon is "GTG". Thus, DNA33100 has a sequence identical to that shown in SEQ ID NO: 147 of the above-identified patent application.

8. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that these statements are made with the knowledge that willful statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the

validity of the application or any patent granted thereon.

Dated: May 7, 2004

Audrey Goddard
AUDREY GODDARD

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5/7/04 12:47 PM (39780.1618)

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PROFESSIONAL EXPERIENCE

Genentech, Inc. 1993-present
South San Francisco, CA

2001 - present Senior Clinical Scientist
Experimental Medicine / BioOncology, Medical Affairs

Responsibilities:

- Companion diagnostic oncology products
- Acquisition of clinical samples from Genentech's clinical trials for translational research
- Translational research using clinical specimen and data for drug development and diagnostics
- Member of Development Science Review Committee, Diagnostic Oversight Team, 21 CFR Part 11 Subteam

Interests:

- Ethical and legal implications of experiments with clinical specimens and data
- Application of pharmacogenomics in clinical trials

1998 - 2001 Senior Scientist
Head of the DNA Sequencing Laboratory, Molecular Biology Department, Research

Responsibilities:

- Management of a laboratory of up to nineteen –including postdoctoral fellow, associate scientist, senior research associate and research assistants/associate levels
- Management of a \$750K budget
- DNA sequencing core facility supporting a 350+ person research facility.
- DNA sequencing for high throughput gene discovery, - ESTs, cDNAs, and constructs
- Genomic sequence analysis and gene identification
- DNA sequence and primary protein analysis

Research:

- Chromosomal localization of novel genes
- Identification and characterization of genes contributing to the oncogenic process
- Identification and characterization of genes contributing to inflammatory diseases
- Design and development of schemes for high throughput genomic DNA sequence analysis
- Candidate gene prediction and evaluation

1993 - 1998 Scientist

Head of the DNA Sequencing Laboratory, Molecular Biology Department, Research

Responsibilities

- *DNA sequencing core facility supporting a 350+ person research facility.*
- *Assumed responsibility for a pre-existing team of five technicians and expanded the group into fifteen, introducing a level of middle management and additional areas of research*
- *Participated in the development of the basic plan for high throughput secreted protein discovery program – sequencing strategies, data analysis and tracking, database design*
- *High throughput EST and cDNA sequencing for new gene identification.*
- *Design and implementation of analysis tools required for high throughput gene identification.*
- *Chromosomal localization of genes encoding novel secreted proteins.*

Research:

- *Genomic sequence scanning for new gene discovery.*
- *Development of signal peptide selection methods.*
- *Evaluation of candidate disease genes.*
- *Growth hormone receptor gene SNPs in children with Idiopathic short stature*

Imperial Cancer Research Fund

1989-1992

London, UK with Dr. Ellen Solomon

6/89 – 12/92 Postdoctoral Fellow

- Cloning and characterization of the genes fused at the acute promyelocytic leukemia translocation breakpoints on chromosomes 17 and 15.
- Prepared a successfully funded European Union multi-center grant application

McMaster University

1983

Hamilton, Ontario, Canada with Dr. G. D. Sweeney

5/83 – 8/83: NSERC Summer Student

- *In vitro metabolism of β-naphthoflavone in C57BL/6J and DBA mice*

EDUCATION

Ph.D.

"Phenotypic and genotypic effects of mutations in the human retinoblastoma gene."

Supervisor: Dr. R. A. Phillips

University of Toronto

Toronto, Ontario, Canada.

1989

Department of Medical Biophysics.

Honours B.Sc

"The *in vitro* metabolism of the cytochrome P-448 inducer β-naphthoflavone in C57BL/6J mice."

Supervisor: Dr. G. D. Sweeney

McMaster University,

Hamilton, Ontario, Canada.

1983

Department of Biochemistry

ACADEMIC AWARDS

Imperial Cancer Research Fund Postdoctoral Fellowship	1989-1992
Medical Research Council Studentship	1983-1988
NSERC Undergraduate Summer Research Award	1983
Society of Chemical Industry Merit Award (Hons. Biochem.)	1983
Dr. Harry Lyman Hooker Scholarship	1981-1983
J.L.W. Gill Scholarship	1981-1982
Business and Professional Women's Club Scholarship	1980-1981
Wyerhauser Foundation Scholarship	1979-1980

INVITED PRESENTATIONS

Genentech's gene discovery pipeline: High throughput identification, cloning and characterization of novel genes. Functional Genomics: From Genome to Function, Litchfield Park, AZ, USA. October 2000

High throughput identification, cloning and characterization of novel genes. G2K:Back to Science, Advances in Genome Biology and Technology I. Marco Island, FL, USA. February 2000

Quality control in DNA Sequencing: The use of Phred and Phrap. Bay Area Sequencing Users Meeting, Berkeley, CA, USA. April 1999

High throughput secreted protein identification and cloning. Tenth International Genome Sequencing and Analysis Conference, Miami, FL, USA. September 1998

The evolution of DNA sequencing: The Genentech perspective. Bay Area Sequencing Users Meeting, Berkeley, CA, USA. May 1998

Partial Growth Hormone Insensitivity: The role of GH-receptor mutations in Idiopathic Short Stature. Tenth Annual National Cooperative Growth Study Investigators Meeting, San Francisco, CA, USA. October, 1996

Growth hormone (GH) receptor defects are present in selected children with non-GH-deficient short stature: A molecular basis for partial GH-insensitivity. 76th Annual Meeting of The Endocrine Society, Anaheim, CA, USA. June 1994

A previously uncharacterized gene, myl, is fused to the retinoic acid receptor alpha gene in acute promyelocytic leukemia. XV International Association for Comparative Research on Leukemia and Related Disease, Padua, Italy. October 1991

PATENTS

Goddard A, Godowski PJ, Gurney AL. NL2 Tie ligand homologue polypeptide. Patent Number: 6,455,496. Date of Patent: Sept. 24, 2002.

Goddard A, Godowski PJ and Gurney AL. NL3 Tie ligand homologue nucleic acids. Patent Number: 6,426,218. Date of Patent: July 30, 2002.

Godowski P, Gurney A, Hillan KJ, Botstein D, **Goddard A, Roy M, Ferrara N, Tumas D, Schwall R.** NL4 Tie ligand homologue nucleic acid. Patent Number: 6,4137,770. Date of Patent: July 2, 2002.

Ashkenazi A, Fong S, **Goddard A, Gurney AL, Napier MA, Tumas D, Wood WI.** Nucleic acid encoding A-33 related antigen poly peptides. Patent Number: 6,410,708. Date of Patent: Jun. 25, 2002.

Botstein DA, Cohen RL, **Goddard AD, Gurney AL, Hillan KJ, Lawrence DA, Levine AJ, Pennica D, Roy MA and Wood WI.** WISP polypeptides and nucleic acids encoding same. Patent Number: 6,387,657. Date of Patent: May 14, 2002.

Goddard A, Godowski PJ and Gurney AL. Tie ligands. Patent Number: 6,372,491. Date of Patent: April 16, 2002.

Godowski PJ, Gurney AL, **Goddard A and Hillan K.** TIE ligand homologue antibody. Patent Number: 6,350,450. Date of Patent: Feb. 26, 2002.

Fong S, Ferrara N, **Goddard A, Godowski PJ, Gurney AL, Hillan K and Williams PM.** Tie receptor tyrosine kinase ligand homologues. Patent Number: 6,348,351. Date of Patent: Feb. 19, 2002.

Goddard A, Godowski PJ and Gurney AL. Ligand homologues. Patent Number: 6,348,350. Date of Patent: Feb. 19, 2002.

Attie KM, Carlsson LMS, Gesundheit N and **Goddard A.** Treatment of partial growth hormone insensitivity syndrome. Patent Number: 6,207,640. Date of Patent: March 27, 2001.

Fong S, Ferrara N, **Goddard A, Godowski PJ, Gurney AL, Hillan K and Williams PM.** Nucleic acids encoding NL-3. Patent Number: 6,074,873. Date of Patent: June 13, 2000

Attie K, Carlsson LMS, Gesunheit N and **Goddard A.** Treatment of partial growth hormone insensitivity syndrome. Patent Number: 5,824,642. Date of Patent: October 20, 1998

Attie K, Carlsson LMS, Gesunheit N and **Goddard A.** Treatment of partial growth hormone insensitivity syndrome. Patent Number: 5,646,113. Date of Patent: July 8, 1997

Multiple additional provisional applications filed

PUBLICATIONS

- Seshasayee D, Dowd P, Gu Q, Erickson S, **Goddard AD**. Comparative sequence analysis of the *HER2* locus in mouse and man. Manuscript in preparation.
- Abuzzahab MJ, **Goddard A**, Grigorescu F, Lautier C, Smith RJ and Chernausek SD. Human IGF-1 receptor mutations resulting in pre- and post-natal growth retardation. Manuscript in preparation.
- Aggarwal S, Xie, M-H, Foster J, Frantz G, Stinson J, Corpuz RT, Simmons L, Hillan K, Yansura DG, Vandlen RL, **Goddard AD** and Gurney AL. FHFR, a novel receptor for the fibroblast growth factors. Manuscript submitted.
- Adams SH, Chui C, Schilbach SL, Yu XX, **Goddard AD**, Grimaldi JC, Lee J, Dowd P, Colman S., Lewin DA. (2001) BFIT, a unique acyl-CoA thioesterase induced in thermogenic brown adipose tissue: Cloning, organization of the human gene, and assessment of a potential link to obesity. *Biochemical Journal* **360**: 135-142.
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- Xie M-H, Aggarwal S, Ho W-H, Foster J, Zhang Z, Stinson J, Wood WI, **Goddard AD** and Gurney AL. (2000) Interleukin (IL)-22, a novel human cytokine that signals through the interferon-receptor related proteins CRF2-4 and IL-22R. *Journal of Biological Chemistry* **275**: 31335-31339.
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- Guo S, Yamaguchi Y, Schilbach S, Wada T.;Lee J, **Goddard A**, French D , Handa H, Rosenthal A. (2000) A regulator of transcriptional elongation controls vertebrate neuronal development. *Nature* **408**: 366-369.
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- Sehl PD, Tai JTN, Hillan KJ, Brown LA, **Goddard A**, Yang R, Jin H and Lowe DG. (2000) Application of cDNA microarrays in determining molecular phenotype in cardiac growth, development, and response to injury. *Circulation* **101**: 1990-1999.
- Guo S, Brush J, Teraoka H, **Goddard A**, Wilson SW, Mullins MC and Rosenthal A. (1999) Development of noradrenergic neurons in the zebrafish hindbrain requires BMP, FGF8, and the homeodomain protein soulless/Phox2A. *Neuron* **24**: 555-566.
- Stone D, Murone, M, Luoh, S, Ye W, Armanini P, Gurney A, Phillips HS, Brush, J, **Goddard A**, de Sauvage FJ and Rosenthal A. (1999) Characterization of the human suppressor of fused; a negative regulator of the zinc-finger transcription factor Gli. *J. Cell Sci.* **112**: 4437-4448.
- Xie M-H, Holcomb I, Deuel B, Dowd P, Huang A, Vagts A, Foster J, Liang J, Brush J, Gu Q, Hillan K, **Goddard A** and Gurney, A.L. (1999) FGF-19, a novel fibroblast growth factor with unique specificity for FGFR4. *Cytokine* **11**: 729-735.

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- Stone DM, Hynes M, Armanini M, Swanson TA, Gu Q, Johnson RL, Scott MP, Pennica D, **Goddard A**, Phillips H, Noll M, Hooper JE, de Sauvage F and Rosenthal A. (1996) The tumour-suppressor gene patched encodes a candidate receptor for Sonic hedgehog. *Nature* 384(6605): 129-34.
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- Mark MR, Scadden DT, Wang Z, Gu Q, **Goddard A** and Godowski PJ. (1994) Rse, a novel receptor-type tyrosine kinase with homology to Axl/Ufo, is expressed at high levels in the brain. *Journal of Biological Chemistry* **269**: 10720-10728.
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